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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,534	04/07/2006	Gunnar Nordvall	101219-1P US	8928

22466 7590 02/19/2008

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EXAMINER	
MOORE, SUSANNA	

ART UNIT	PAPER NUMBER
1624	

MAIL DATE	DELIVERY MODE
02/19/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/575,534	NORDVALL ET AL.	
	Examiner	Art Unit	
	SUSANNA MOORE	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-20* is/are pending in the application.

4a) Of the above claim(s) *17-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/26/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group (I), claims 11-16 in the reply filed on 12/21/2007 is acknowledged.

This application contains claims drawn to an invention nonelected without traverse in the reply filed on 12/21/2007. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

In summary, claims 11-20 are currently pending. Claims 11-16 are drawn to thiazolo[4,5-d]pyrimdines and simple compositions thereof. Claims 17-20 are currently withdrawn from consideration.

Claim Objections

Claim 1 is objected to because of the following informalities: please replace "CO2R^{11}" with "CO_2R^{11}" on page 4, line 4. Appropriate correction is required.

Claim 15 is objected to because of the following informalities: claim 15 is substantial duplicates of claim 1 as the only difference is a statement of intended use, which is not given material weight. Note *In re Tuominen* 213 USPQ 89.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 recites the limitation "C1 to 6 alkoxy" in line 2 of said claim. There is insufficient antecedent basis for this limitation in the claim.

Claims 11-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compounds of Formula 1, wherein R^1 and R^2= alkyl and cycloalkyl and R^{22} and R^{23}= hydrogen does not reasonably provide enablement for compounds of Formula 1, wherein R^1 and R^2= alkenyl and alkynyl and R^{22} and R^{23}= independently represent C1 to 6 alkyl, C2 to 6 alkenyl or C3 to 7 saturated or partially unsaturated cycloalkyl; said alkyl, alkenyl or cycloalkyl group being optionally substituted by OR^{24}, $NR^{24}R^{25}$, CO_2R^{24} or $CONR^{24}R^{25}$; or the

group -$NR^{22}R^{23}$ together represents a 3 to 7 membered saturated azacyclic ring optionally incorporating one further • heteroatom selected from O, $S(O)_n$ and NR^{26}; and optionally substituted by OR^{24}, $NR^{24}R^{25}$, CO_2R^{24} or $CONR^{24}R^{25}$. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Pursuant to In re Wands, 858 F.2d 731,737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988), one considers the following factors to determine whether undue experimentation is required: (A) The breadth of the claims; (B) The nature of the invention; (C) The state of the prior art; (D) The level of one of ordinary skill; (E) The level of predictability in the art; (F) The amount of direction provided by the inventor; (G) The existence of working examples; and (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure. Some experimentation is not fatal; the issue is whether the amount of experimentation is "undue"; see In re Vaeck, 20 USPQ2d 1438, 1444.

The analysis is as follows:

(A) Breadth of claims: Scope of the compounds. Owing to the range of many variables, thousands of substituted thiazolo[4,5-d]pyrimidines are embraced.

(B) The nature of the invention: The invention is a highly substituted thiazolo[4,5-d]pyrimidines.

(C) Level of predictability in the art: It is well established that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved," and physiological activity is generally considered to be an unpredictable factor. See *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

(D) Direction or Guidance: That provided is very limited. Applicant shows a general synthesis of compounds of Formula 1, under Preparation on pages 102-132 of the Specification, but does not show the starting material used to make the variety of compounds claimed. There is limited evidence in the Specification of the example compounds that only cover a small portion of the substituents claimed of Formula 1. Thus, there is no specific direction or guidance regarding said compounds of Formula 1 specifically mentioned in Scope.

The specification does not provide any support for the synthesis of compounds of Formula 1, wherein R^1 and R^2= alkenyl and alkynyl and R^{22} and R^{23}= independently represent C1 to 6 alkyl, C2 to 6 alkenyl or C3 to 7 saturated or partially unsaturated cycloalkyl; said alkyl, alkenyl or cycloalkyl group being optionally substituted by OR^{24}, $NR^{24}R^{25}$, CO_2R^{24} or $CONR^{24}R^{25}$; or the group $-NR^{22}R^{23}$ together represents a 3 to 7 membered saturated azacyclic ring optionally incorporating one further • heteroatom selected from O, $S(O)_n$ and NR^{26}; and optionally substituted by OR^{24}, $NR^{24}R^{25}$, CO_2R^{24} or $CONR^{24}R^{25}$.

The availability of the starting material that is needed to prepare the invention as claimed is at issue here...As per MPEP 21'64.01 (b). A key issue that can arise when determining whether the specification is enabling is whether the starting materials or apparatus necessary to a make the invention are available. In the biotechnical area, this is often true when the product or process

requires a particular strain of microorganism and when the microorganism is available only after extensive screening. The Court in *In re Ghiron*, 442 F.2d 985, 991,169 USPQ 723, 727 (CCPA 1971), made it clear that if the practice of a method requires a particular apparatus, the application must provide a sufficient disclosure of the apparatus if the apparatus is not readily available. The same can be said if certain chemicals are required to make a compound or practice a chemical process. *In re Howarth*, 654 F.2d 103, 105, 210 USPQ 689, 691 (CCPA 1981).

(E) State of the Prior Art: These compounds are substituted thiazolo[4,5-d]pyrimidines of Formula I wherein R^1 and R^2= alkyl and cycloalkyl and R^{22} and R^{23}= hydrogen which are well documented in the art. So far as the examiner is aware, no substituted thiazolo[4,5-d]pyrimidines of Formula I wherein R^1 and R^2= alkenyl and alkynyl and R^{22} and R^{23}= independently represent C1 to 6 alkyl, C2 to 6 alkenyl or C3 to 7 saturated or partially unsaturated cycloalkyl; said alkyl, alkenyl or cycloalkyl group being optionally substituted by OR^{24}, $NR^{24}R^{25}$, CO_2R^{24} or $CONR^{24}R^{25}$; or the group $-NR^{22}R^{23}$ together represents a 3 to 7 membered saturated azacyclic ring optionally incorporating one further • heteroatom selected from O, $S(O)_n$ and NR^{26}; and optionally substituted by OR^{24}, $NR^{24}R^{25}$, CO_2R^{24} or $CONR^{24}R^{25}$ of any kind have been made or used.

(F) Working Examples: Applicant shows examples on pages 10-13 but no working examples were shown of Formula I wherein R^1 and R^2= alkenyl and alkynyl and R^{22} and R^{23}= independently represent C1 to 6 alkyl, C2 to 6 alkenyl or C3 to 7 saturated or partially unsaturated cycloalkyl; said alkyl, alkenyl or cycloalkyl group being optionally substituted by

OR^{24}, $NR^{24}R^{25}$, CO_2R^{24} or $CONR^{24}R^{25}$; or the group $-NR^{22}R^{23}$ together represents a 3 to 7 membered saturated azacyclic ring optionally incorporating one further • heteroatom selected from O, $S(O)_n$ and NR^{26}; and optionally substituted by OR^{24}, $NR^{24}R^{25}$, CO_2R^{24} or $CONR^{24}R^{25}$ of any kind have been made or used.

(G) Skill of those in the art: The ordinary artisan is highly skilled.

(H) The quantity of experimentation needed: Since there are very limited working examples as described above, the amount of experimentation is expected to be high and burdensome.

Due to the level of unpredictability in the art, the very limited guidance provide, and the lack of working examples, the Applicant has shown lack of enablement for the groups noted groups on Formula i. MPEP 2164.01(a) states, "A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is clearly justified here.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSANNA MOORE whose telephone number is (571)272-9046. The examiner can normally be reached on M-F 8:00-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susanna Moore/
Examiner, Art Unit 1624

/Brenda L. Coleman/
Primary Examiner, Art Unit 1624